K071353

SECTION 5. 510(K) SUMMARY

Submission Correspondent:	Keystone Regulatory Services, LLC 342 E. Main Street Suite 211 Leola, PA 17557 USA Phone: 717-656-9656 Fax: 717-656-3434 Email: bill.mclain@keystoneregulatory.com Contact: William G. McLain President and Principal Consultant
Submission Sponsor:	Shanghai Foshion Medical Instrument Company, Ltd No.211 Jiangchang No.3 Rd Zhabei Borough Shanghai, China Phone: 86-21 51097191 Fax: 86-21 51060057
Date summary prepared:	May 15, 2007
Device trade name:	Foshion Chair Mounted Dental Unit
Device common name:	Dental chair with operative unit.
Device classification name:	EIA, Dental Operative Unit, 21 CFR 872.6640
Legally marketed device to which the device is substantially equivalent:	F1 Series Dental Chairs with Operative Unit, K052470. Manufactured by Shanghai Fimet Medical Instrument Co., Ltd.
Description of the device:	The Foshion Chair Mounted Dental Unit is a dental operative unit attached to a dental chair. There are three main parts to the product: a dental chair, a dental unit, and a stool for the dentist. The dental chair has adjustable headrest, backrest, seat with extension for leg support, and armrests. The dental unit consists of a floor box to which are attached a number of operative units: light, x-ray viewer, cuspidor, cup filling device, control panel, instrument tray, and foot control. The instrument panel also includes a 3-way syringe, saliva ejector, air suction, and handpiece attachments

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Intended use of the device:	The Foshion Chair Mounted Dental Unit is intended to supply power and serve as a base for dental devices and accessories. The product includes a dental chair, operating light, x-ray viewer, control panel, low and high speed turbine hand pieces, 3-way syringe and air foot control. The unit is intended for use in the dental office or clinic and is used by trained dentists and/or dental technicians and assistants.
Technological characteristics:	The technological characteristics between the predicate and proposed device are similar. Both are chair mounted dental units which supply power and serve as a base for dental devices and accessories.
Conclusions:	There are no significant differences between the Foshion Chair Mounted Dental Unit and the predicate device; therefore, the proposed device does not raise any questions regarding safety and effectiveness. The Foshion Chair Mounted Dental Unit, as designed, is as safe and effective as the predicate device. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Keystone Regulatory Services, LLC
C/O Mr. William Mclain
Principal Consultant
Shanghai Foshion Medical Instruments Company, Limited
342 East Main Street, Suite 211 No. 3 Road
Leola, Pennsylvania 17540

Re: K071353
Trade/Device Name: Chair Mounted Dental Unit
Regulation Number: 872.6250
Regulation Name: Dental Chair and Accessories
Regulatory Class: II
Product Code: KLC
Dated: November 28, 2007
Received: December 6, 2007

Dear Mr. Mclain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

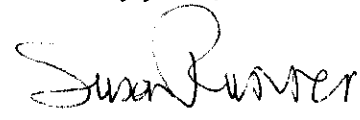
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K071353

Device Name: Chair Mounted Dental Unit

Indications for Use: The Foshion Chair Mounted Dental Unit is intended to supply power and serve as a base for dental devices and accessories. The product includes a dental chair, operating light, x-ray viewer, control panel, low and high speed turbine hand pieces, 3-way syringe and air foot control. The unit is intended for use in the dental office or clinic and is used by trained dentists and/or dental technicians and assistants.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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